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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,896	09/26/2001	Preeti Lal	PF-0527-2 DIV	2122

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	4

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/963,896	LAL ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 17, 18 and 56 drawn to an isolated polypeptide identified as SEQ ID NO: 1, classified in class 530, subclass 350. Claims 1, 2, 17 and 18 will be examined with Group I to the extent the polypeptide is SEQ ID NO: 1.

II. Claims 1, 2, 17, 18 and 57, drawn to an isolated polypeptide identified as SEQ ID NO: 2, classified in class 530, subclass 350. Claims 1, 2, 17 and 18 will be examined with Group II to the extent the polypeptide is SEQ ID NO: 2.

III. Claims 3-7, 9, 10, 12, 13, and 58, drawn to an isolated polynucleotide identified as SEQ ID NO: 3, classified in class 536, subclass 23.1. Claims 3-7, 9, 10, 12 and 13 will be examined with Group III to the extent the polynucleotide is SEQ ID NO: 3.

IV. Claims 3-7, 9, 10, 12, 13, and 59, drawn to an isolated polynucleotide identified as SEQ ID NO: 4, classified in class 536, subclass 23.1. Claims 3-7, 9, 10, 12 and 13 will be examined with Group IV to the extent the polynucleotide is SEQ ID NO: 4.

V and VI. Claim 8, drawn to a transgenic organism comprising a recombinant polynucleotide, which is SEQ ID NO: 3 or SEQ ID NO: 4, respectively, classified in class 800, subclass 8.

VII and VIII. Claims 11, 21, 24, 31, 32, 34 and 36-43, drawn to an isolated antibody which binds to the polypeptide identified as SEQ ID NO: 1 or SEQ ID NO: 2, respectively, classified in class 530, subclass 387.1.

IX and X. Claims 14, 15 and 29, drawn to a method of detecting a target polynucleotide and assessing toxicity of a test compound comprising hybridization, wherein the said target has the sequence of SEQ ID NO: 3 or SEQ ID NO: 4, respectively, classified in class 424, subclass 9.1.

XI and XII. Claim 16, drawn to a method of detecting a target polynucleotide comprising amplifying the said polynucleotides via polymerase chain reaction amplification, wherein the target polynucleotide is SEQ ID NO: 3 or SEQ ID NO: 4, respectively, classified in class 435, subclass 91.2.

XIII and XIV. Claim 19, drawn to a method for treating a disease or condition comprising administering a polypeptide, SEQ ID NO: 1 or SEQ ID NO: 2, respectively, classified in class 514, subclass 2.

XV and XVI. Claims 20, 23, 26 and 27, drawn to a method of screening a compound comprising exposing a polypeptide sample, which may be SEQ ID NO: 1 or SEQ ID NO: 2, respectively, classified in class 435, subclass 7.1.

XVII and XVIII. Claims 22, 25, 33 and 35, drawn to a method for treating and diagnosing a disease or condition comprising administering an antibody, which binds to SEQ ID NO: 1 or SEQ ID NO: 2, respectively, classified in class 424, subclass 130.1.

XIX and XX. Claims 28, drawn to a method of screening a compound comprising exposing a polynucleotide sample, which may be SEQ ID NO: 3 or SEQ ID NO: 4, respectively classified in class 435, subclass 6.

XXI and XXII. Claims 30, 44 and 45, drawn to a diagnostic test comprising combining a biological sample with an antibody that binds to polypeptides, SEQ ID NO: 1 or SEQ ID NO:, respectively, classified in class 435, subclass 7.1.

XXIII and XXIV. Claims 46-55, drawn to microarray wherein the polynucleotide ins SEQ ID NP: 3 or SEQ IDNP : 4, respectively, classified in class 435, subclass 7.92.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-VIII are structurally and functionally different products, which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues. Furthermore, the products of Groups III and IV are DNA, deoxyribonucleic acids, unbranched polymers composed of four subunits, whereas the polypeptides of Groups I and II are a linear order of amino acid residues. The antibody product of Groups VII and VIII are glycoproteins.

The methods of Groups IX-XXIV differ in the method objectives, method steps and parameters and in the reagents used. Furthermore, the method Groups of IX-XII,

XV, XVI and XIX-XXIV involve *in vitro* applications, whereas the methods of Groups XIII, XIV, XVII and XVIII involve *in vivo* therapy.

Inventions V, VI and III, IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups I and II could also be administered to the transgenic organisms of Groups V and VII in order to elicit antibodies.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone

number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
28 September 2003